Utah Department of Health

CLINICAL LABORATORY BULLETIN February 2006

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING:

Karen Keller Chemical Terrorism

NOTEWORTHY

✓ **Diagnosing rheumatoid arthritis (RA):** Anti-cyclic citrullinated peptide (anti-CCP) antibody test, in conjunction with the age old rheumatoid factor (RF) test, could help clinicians pin down that elusive RA diagnosis. While RF is more sensitive (75–85% compared to 60%), anti-CCP is more specific than RF (98-99% compared to 60-65%).

The October 2002 *Journal of Rheumatology* had an article stating the two tests together were better than RF alone for diagnosing patients with early, undifferentiated RA.

Two companies currently offer ELISA kits for anti-CCP testing – Axis-Shield Diagnostics of Dundee, Scotland and Euro-Diagnostica of Arnhem, The Netherlands. Axis-Shield Diagnostics hopes to have the assay on its AxSYM automated system soon.

✓ **Contaminated GC Cultures:** Have you seen an increase in overgrown GC cultures recently? Maryland's Department of Health & Mental Hygiene has. After extensive investigation by the offending media's (Transgrow bottles) manufacturer and the health department, no cause was found. Contamination over growth was four times normal. Maryland is now doing parallel checks with other manufacturer's media to determine if patient's normal flora are overwhelming the antibiotics in Transgrow bottles. Stay tuned!

✓ **Phlebotomy error prevention:** Accurate test results can only be produced from a quality patient specimen. Here are some items to review before you collect a blood specimen:

- Identify your patient using a method that assures you have the correct patient (name tag, patient gives name and birth date, etc.) even if you think you know the person.
- By national standard, a tourniquet may be left on the patient's arm no longer than one minute. If you have a number of tubes to draw, or it takes some time to locate the vein, take the tourniquet off when the blood begins to fill the tube.
- Coagulation tubes not filled to the proper level will cause a false increase in the INR.
- A patient with a high hematocrit (polycythemic) will not have enough plasma for the amount of anti-coagulant in the standard tube. The lab will need to make a calculation for how much

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citrate to use for such a patient to avoid false prothrombin time results.

- Avoid a lot of fishing for the basilic vein, you may cause permanent nerve damage by hitting a nerve. See the "Safety" section of this bulletin for vein finding aids.
- Ask the patient where they think the best puncture site would be. Sometimes they know! If the patient complains of a shooting pain during the phlebotomy, stop the procedure immediately.
- Be certain to wear appropriate protective equipment – correctly – to protect yourself when collecting blood.

✓ **Safe platelets:** The American Association of Blood Banks (AABB) published a standard requiring platelet packs be cultured for bacterial contamination prior to release for use.

Dr. Brecher of the University of North Carolina at Chapel Hill stated in the September 2005 CAP Today that screening platelet packs by pH or glucose is not sensitive enough to determine bacterial growth. Dr. AuBuchon stated in the same article, 1 of every 5,000 platelet units is found to contain bacteria.

Two manufacturers are developing cell separator devices to reduce contamination. Gambro BCT Inc. was approved by the FDA in March to offer a seven day storage limit for platelets prepared with their separator. They tested their product with aerobic and anaerobic cultures using a BacT/Alert. Pall Medical should have a similar device approved soon. Their device will not detect strict anaerobes.

Prions – search and destroy: The name "prion" is an anagram of "proin". This word is derived from **pro**teinaceous **in**fectious particle. The most famous member of this infectious group causes new variant Cretuzfeldt-Jakob disease (a variant of mad cow disease). Scrapie was the first recognized disease now known to be caused by prions.

A prion is a small piece of protein without nucleic acid that inserts itself into host cells and convinces them to make "little" prions. Detecting prions can only be done by Western blot analysis of a tissue biopsy. By summer a blood test may be available. Research continues on a likely candidate at the University of Texas Medical Branch.

Prions can survive several years in the environment. They are resistant to ethanol, formaldehyde, deoxycholate, *B*-propiolactone, proteases and ionizing radiation. The good news is they are sensitive to 90% phenol, 5% hypochlorite (household bleach), ether, acetone, strong detergents, iodine disinfectants and "special" autoclaving.

Guanidine thiocyanate is good for decontaminating medical supplies, instruments and tissues. Autoclaving at 15 psi for **one hour,** bleach or 1.0 molar sodium hydroxide can also be used to decontaminate.

Information provided by the Maryland Department of Health & Mental Hygiene's publication **Critical Link**, November 2005.

✓ **Glucometer test strip stability:** Follow the manufacturer's instructions to keep test strips at room temperature, in the dark and dry. Student researchers at East Carolina University published the findings of their research into test strip stability in the Fall 2005 issue of Clinical Laboratory Science. They found strips stored in open vials lost accuracy in 35-50 days. Adding light or moisture to open vial storage and stability dropped accuracy in 3-14 days.

The students stated new methodology (electro-chemical detection) test strips were not tested. Some manufacturers are storing strips wrapped individually in foil to prevent deterioration. Follow the manufacturer's storing instructions – even a simple CLIA "waived" test can have serious patient outcome failures if the instructions are not followed exactly.

✓ **West Nile Virus (WNV) in blood transfusions:** The FDA made changes to their blood donor policies to prevent WNV from being transfused from donor blood to recipients. They lengthened the donation deferral period for persons diagnosed or suspected of having WNV infection from 28 to 120 days. They did drop the donation screening questions about fever or headache during the previous week. AABB objects to the longer waiting period for deferred donors as the decision was based on a single case.

The risk of transfusion related infectious disease in the US is quantifiable for hepatitis B and C, for HIV and for HTLV. The risk is too uncommon for syphilis and CMV to be quantified. WNV however is listed as a risk depending on the region of the country the donor is in and the season of the year.

Tests for WNV antibody are available from Focus Diagnostics and PanBio Limited. Nucleic acid amplification tests for screening blood donors are available from Roche Diagnostics and Gen-Probe Inc. & Chiron Corp.

✓ **Diabetic Ketoacidosis (DKA) or Hyperosmolar Hyperglycemia Syndrome (HHS)?:** You have a diabetic patient that is in a stupor or coma and unable to talk to you. Is the patient in DKA or HHS? Linda S. Gorman, PhD, CLS feels the deciding test is *B*-hydroxybutyric acid (B-hBA). While this is one of the ketones the body forms, the ketone detection method in urine strips, tablets and serum ketone rapid assays does not measure B-hBA. "In HHS patients the upswing in fatty acid metabolism could lead to increased acetoacetate, but not the ketosis that is seen when B-hBA increases. In the DKA patient where ketosis exists, the B-hBA levels are 75% of the elevation in ketones seen."

So a positive rapid test for ketones could be seen in either condition. Only the B-hBA test can accurately differentiate the two conditions according to Dr. Gorman. Differentiation is critical for children or adolescent diabetics as they are susceptible to cerebral edema in DKA.

✓ **FDA explains recent blood glucose meter recall: (**See recall notice in the safety section of this bulletin.) If you have a whole blood glucose meter made by Abbott Diabetes Care (model numbers listed the safety section of this bulletin) check the FDA website at www.fda.gov/medwatch for additional information. It seems the meters were made to be used in the US and report results in mg/dL or to be used in foreign countries reporting results in mmol/L. There is a switch to change from one reading to the other. Reports of persons inadvertently changing to the wrong measurements while setting the date and time or changing the battery reached FDA. Also persons reported the meter switching after being dropped. Abbott has corrected the problem on newer lots now being shipped to distributors. What a great "heads up". We are so used to taking the answer from an instrument and putting it in a report, we don't always look closely at the result.

✓ **Adult acellular pertussis vaccine**: Infants are immunized against whooping cough during the first few months of life. The immunization is very effective. Now we know that adolescents and adults can become infected with *Bordetella pertussis*. They may have a mild "cold" or much more serious illness resulting in prolonged coughing, cracked ribs and hospitalization with pneumonia. Not to mention, adults can pass the bacteria to susceptible infants and children who can develop more serious disease.

Vaccine researchers at the University of California, Los Angeles, said their trials showed one dose of the adult vaccine to be 90% effective in preventing infection. The national, large-scale clinical study was published in the *New England Journal of Medicine*.

FROM THE PATIENT'S CHART

"The patient was alert and unresponsive."

☆ Feature ☆

COMMON MYCOBACTERIUM SPECIES - NOT TUBERCULOSIS - IDENTIFIED AT THE UTAH PUBLIC HEALTH LAB

Mycobacterium avium complex (MAC)

These organisms have been isolated from water, soil, plants and other environmental sources. Generally they are of low pathogenicity. They are the most common mycobacterium isolated from AIDS patients. Prior to AIDS, MAC was usually a pulmonary disease showing several different clinical patterns such as tuberculosis-like infiltrates, nodular bronchiectasis, and diffuse infiltrates in immunocompromised patients.

MAC typically occurs in white males 45 to 60 years of age who are heavy smokers, abuse alcohol and/or have a pre-existing lung disease. Clinical presentation is similar to tuberculosis. MAC is well known for heterogeneous colony morphology (glossy, whitish colonies that appear with smaller translucent ones). A third colony type, resembling the dry flat colonies of *M. tuberculosis,* is more rare.

Mycobacterium chelonae

This organism is a rapid grower. It is usually found in immunocompromised patients. The most common clinical presentation is a disseminated nodular skin disease with draining lesions. The environmental reservoir is unknown. It is rarely found in tap water.

Mycobacterium gordonae

This is the most commonly encountered "non-pathogenic" organism in the Mycobacteriology lab. It is widely found in soil and water.

Mycobacterium fortuitum group

Members of this group are responsible for various sporadic infections including osteomyelitis, cellulites, surgical and post-traumatic wound infections, central catheter related infections, and rarely in chronic pulmonary disease.

They grow rapidly – usually between 1 and 3 days. They are found in natural and tap water, soil, dust and mud.

Mycobacterium kansasii

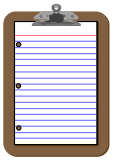
This organism is second only to MAC as a cause of non-tuberculosis lung disease. It is found in tap water throughout the world. It is a common infection in mine workers in the United Kingdom and South Africa.

Chronic pulmonary disease resembling classical tuberculosis is the most common manifestation, often involving the upper lobes. *M. kansasii* rarely disseminates except in patients with severely impaired cellular immunity (AIDS, organ transplant, etc.).

Mycobacterium marinum

This organism causes cutaneous infections as a result of trauma to the skin with exposure to seawater (salt water) or contaminated freshwater fish tanks. The most typical presentation is a single papulonodular lesion confined to one extremity. The lesion appears 2 to 3 weeks after inoculation and may become veracious or ulcerated.

Stephanie McGee
UPHL Microbiologist



CLIA BITS

ADDITIONAL WAIVED TESTS:

° Hemocue Glucose 201 DM Analyzer

°SA Scientific SAS Influenza A Test, Influenza B Test

°Worldwide Medical First Check Multi Drug Cup 7 (OTC)

°IND Diagnostic Inc. One Step FSH Menopausal Test (midstream, professional use, strip and cassette) and One Step Cassette Style FSH Menopausal Test (professional use)

°BinaxNOW Influenza A & B Test (nasopharyngeal swab and nasal wash/aspirate specimens)

°QuickVue iFOB Test (fecal occult blood – cassette)

°Rapid Response Mononucleosis Rapid Test Device (whole blood)

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As of January 5, 2006 there is only one (of 65) FDA approved fecal occult blood test system that is **NOT** waived – Polymedco OC Auto Micro 80 analyzer. This test is categorized moderately complex.

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CPT Codes

These 9 HCPCS codes were **discontinued** 12/31/2005: 0010T; 78160; 82273; 83715; 83716; 86064; 86379; 86585; 86587.

Three new codes were added (excluded from CLIA edits for 2006): 86923; 86960; 87900.

Two new waived test codes: 82272; 83037.

Twenty six new non-waived codes were added. Check the Medicare bulletin or website.

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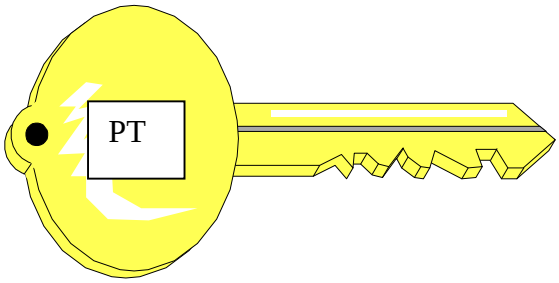
On November 11, 2005 the CDC published a report called "Good Laboratory Practices for Waived Testing Sites" in the Morbidity and Mortality Weekly Report (MMWR). The report summarizes study findings and provides recommendations developed by the Clinical Laboratory Improvement Advisory Committee (CLIAC) for conducting quality waived testing. The report is available at: www.cdc.gov/mmwr/preview/mmwrhtm/rr5413al.htm.

Equals

"Basic unit of laryngitis: 1 hoarsepower."



Remember CLIA requires a laboratory to rotate proficiency testing among all employees who do patient testing.

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If you test an analyte on more than one instrument (back up method or duplicate such as CO_2 on your routine chemistry analyzer and on an iSTAT with the blood gases), make certain you have some method of assuring the accuracy of each instrument's results. You may do this by enrolling both in proficiency testing; checking results of the alternate method with the primary method on patient samples; testing known samples from another lab; etc. Just be certain you note the quality assurance checks, or grade the extra proficiency test results and note the method's accuracy at least twice each calendar year.

SAFETY

The FDA sent a notice to alert physicians, nurses, medical technologists, pharmacists and other healthcare professionals November 9, 2005 of the potential for life-threatening falsely elevated glucose readings in patients using a dehydrogenase pyrroloquinoline-quinone (GDH-PQQ) method and receiving parenteral products containing maltose or galactose or oral xylose. The GDH-PQQ glucose monitoring method is non-specific for glucose and, in the presence of maltose, galactose or xylose may yield falsely elevated glucose readings. The FDA advised healthcare providers who prescribe a GDH-PQQ method to individuals monitoring their own blood sugar at home, to tell any patients receiving a product containing the interfering sugars their test results may be false. The patients should obtain a glucose monitoring device that is not subject to the interference. The complete notice is available on the FDA site: www.fda.gov/cber/safety/maltose110405.htm.

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On January 16, 2006 Roche Diagnostics initiated a voluntary recall of specific Accu-Chek Aviva whole blood glucose meters because of a potential for an electronic malfunction which could cause the meter to report erroneous results or shut down and no longer be usable. (See information on the specific problem in the Noteworthy section of this bulletin.) The affected device serial numbers are #52500000000 through #52510999999. For additional information visit the company's website at www.accu-chek.com or call 1-800-858-8072.

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Warning to Persons Receiving WinRho SDF (Rh_0 [D] Immune Globulin Intravenous [human])

Cangene Corporation and Baxter Healthcare Corporation sent an important drug warning letter to persons involved in prescribing, testing, administering and taking their immunoglobulin product. The letter stated two warnings. A revised information sheet for the product will be published later.

1. ITP patients are warned about possible intravascular hemolysis. Patients receiving the immunoglobulin should be warned to report symptoms of hemolysis (back pain, shaking chills, fever, discolored urine, decreased urine output, sudden weight gain, fluid retention/ edema, and/or shortness of breath) to their physician immediately. Serious complications including DIC, have been reported in ITP patients.

2. Patients who regularly monitor their glucose with a method not specific for glucose (GDH-PQQ or glucose-dye-oxidoreductase) may see falsely elevated test results if they received maltose or galactose parenterally or oral xylose (see the related information in the first notice of this section). The company makes one of these products – WinRho SDF.

If you have questions, contact Baxter Medical Affairs at 1-866-424-6724.

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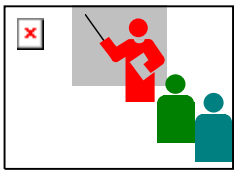
Vein Finding Aids

There are several devices available, or in the approval process, to help phlebotomists locate veins. Some are liquid crystal thermography, some light-emitting diodes (LED), and some infrared light devices. Those available in the US now include the Venoscope (LED); the Transillumination Vein Locator (for neonates, pediatrics and frail adults); and the Vena-Vue (liquid crystal thermography).

Accessing a vein the first time, with minimal discomfort to the patient and speed for the phlebotomists, can only aid in the quality of the specimen. Most of these systems are compact, inexpensive and operate on regular batteries. It just takes a bit of training to become comfortable with their use.

"The greatest thing you can do in your own life is extend yourself in kindness and love to someone else."
Oprah Winfrey

CONTINUING EDUCATION



Clinical Laboratory Science Degree – Available On-line

The University of Nebraska Medical Center is offering a totally on-line degree completion option for certified medical laboratory technicians who wish to become baccalaureate degree clinical laboratory scientists / medical technologists.

For information contact Maggie J. Winnicki, MPH, Distance Education Administrative Coordinator at 800-626-8431, ext. 97627 or email mwittstruck@unmc.edu.

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University of Utah Rocky Mountain Center for Occupational & Environmental Health Presents:

Indoor Mold Contamination: Inspecting & Assessing the Risk March 30, 2006

Indoor Mold Contamination – Choosing and Supervising the Proper Remediation March 31, 2006.

Both courses will be held in Salt Lake City. The faculty is Frank DeRosso, CHI. For a brochure call 801-581-4055. For additional information about these or other environmental courses visit their website at www.rmcoeh.utah.edu/ce.

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University of Cincinnati

Online Bachelor of Science in Clinical Laboratory Science for CLTs and MLTs.

For information call 800-556-4280 or visit www.clsonline.uc.edu.

"On the high road, too, there are potholes."
Dale Dauten